REMARKS

The only issues outstanding in the office action mailed February 15, 2006, are the requirement for restriction and the rejections under 35 U.S.C. §§101 and 112. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Requirement for Restriction

Applicants traversal of the restriction requirement is maintained, for reasons of record. Moreover, it is submitted that the restriction requirement improperly divides the claims *within* a claim, instead of following proper Markush practice, as set forth in M.P.E.P. §803.02. This section of the M.P.E.P. mandates, for a Markush-type claim, an election of species and, where no prior art is found (as in the present case) examining the remaining claim "fully with respect to the elected species and further to the extent if necessary to determine patentability." See M.P.E.P. §803.02, paragraph 4.

Instead, the restriction requirement has divided the claim up among various groups, for example, with claim 1 present in groups I, II and IV. By contrast, M.P.E.P. §803.02 states that, since the decisions of *In re Weber*, 580 F2d 455, 198 U.S.P.Q. 328(C.C.P.A. 1978) and *In re Haas*, 580 F2d 461, 198 U.S.P.Q. 334(C.C.P.A. 1978), it is improper for the office to refuse to examine that which applicants regard as their invention", unless the subject matter of a claim "lacks unity of invention." Unity of invention, of the M.P.E.P. argues, is present where compounds within a Markush group share a common utility, and share a substantial structural feature. As evident from the legal decisions cited in this portion of the M.P.E.P., for example *In re Harnish*, 631 F2d 716, 206 U.S.P.Q. 300 (C.C.P.A. 1980), the present compounds do possess such a common structural feature, for example, the pyrimidine ring in formula I. It is therefore respectfully submitted that, rather than restricting claim 1 into three separate groups, the office action should examine the elected species, and since no art has been found, continue examination up to the full scope of the claim. Withdrawal of the restriction requirement is therefore respectfully requested.

Finally, it is noted that the standard "propriety of the claim," cited at page 2 of the office

action discussing M.P.E.P. §2173.05(h), refers to whether the Markush expression is proper or not, and has nothing to do with the propriety of a restriction.

Rejection under 35 U.S.C. §101

Claims 12, 13 and 18-23 have been rejected under 35 U.S.C. §101. Reformatting of these claims as method claims, for US practice, obviates this rejection. Claims 15, 16 and 23 have been cancelled as being superfluous. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 12-23 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enabling requirement. Reconsideration of this rejection is respectfully requested.

The heart of this rejection, as stated at page 4 of the office action, appears to be based on the breadth of present claims, in view of the argument that the specification does not contain sufficient "evidence" that all indications listed in the claims can be treated as stated in the specification.

First, the specifiation teaches that the compounds of formula I inhibit cyclin-dependent kinases, page 2, and this statement is supported with a discussion of the link between such inhibition and treatment of the recited indications, see page 32. Clearly, this discussion, *without more*, is sufficient to establish utility of the application for purposes of §112 of the statute, as it constitutes a scientifically supportable statement of utility which would be plausible to one of ordinary skill in the art.

It is well established that an unsupported suggestion that reactants within a class defined by claims in a typical method of use application would not work, or that such claims embrace inoperative members, insufficient basis alone for rejecting the claims. See *Ex parte Janin*, 209 U.S.P.Q. 761 (POBA 1979). In fact, it is clear that recitations in an Applicants' specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971).

The first paragraph of 35 U.S.C §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, supra. Applicants' specification clearly enables one to make and use the disclosed compounds in the claimed methods, as evidenced from the disclosure containing pharmaceutical formulations and dosages and the examples which also detail the production of a pharmaceutical formulations.

On the one hand, it is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of utility in the specification other than the breadth of the claims, and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. The "great diversity of diseases" does not rise to the level of such reasons or evidence. As clearly stated in *Marzocchi*, mere *breadth* of the claims does not, without more, result in non-enablement. As the court stated in *Marzocchi*, supra

> Turning specifically to the objections noted by the Board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that Applicants, when they included the disputed terms in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by Applicants that all of the 'considerable number of compounds' which are included in the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only relevant concern of the patent office under these circumstances should be over the *truth* of any such assertion. The first paragraph of §112 requires nothing more than *objective enablement.* How such a teaching is set forth, either by the use of illustrative examples or by broad term analogy, it is of no importance.

Marzocchi, supra. (Emphasis in original.) Thus, the concern expressed at pages 3 and 4 of the Office Action, apparently that the terms used in the claimed methods are broad, does not provide the reasons or evidence necessary by *Marzocchi* to pass beyond the necessity merely for objective

enablement.

Further, in this regard, it is important to note, as a matter of law, that it is not necessary for Applicants' *method* claims to exclude inoperative embodiments, inasmuch as the claims are interpreted in light of the level of understanding one of ordinary skill in the art and, for methods, are interpreted to be *per se* functional. See *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976) and *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (CCPA 1974). These cases state that, for method claims, inoperative embodiments are not encompassed therein and the only question is whether it would be undue experimentation for one of ordinary skill in the art to determine the scope of the claim. This issue is discussed more fully below. Moreover, anti-tumor utilities are no longer to be considered to be "special", i.e., per se incredulous, by the Patent and Trademark Office. See *Ex parte Rubin*, 5 U.S.P.Q. 2d 1461 (BPAI 1987). As such, applications claiming these methods are, therefore, no more than typical method of use applications wherein the existence of reliable screening protocols correlatable with pharmaceutical activity in humans is sufficient to satisfy §112, in the absence of reasons to the contrary. As noted above, screening protocols for determining the efficacy of the compounds in the anti-tumor utilities are set forth in the specification, and the details of using a given compound can be determined by routine testing using a known protocol which is correlated with human activity, see the proliferation at page 173. The PTO has not alleged it would have been undue experimentation to determine the *scope* of the present method claims. It is important to note that a determination of undue experimentation must be considered on a *compound by compound* basis. The mere fact that a claim is broad does *not* mean that it is undue experimentation is required to determine enablement of the compounds therein, if it is not undue experimentation to determine enablement for *each* compound in the scope of the claim. See, for example, *In re Colianni*, 195 U.S.P.Q. 150 (CCPA 1977). One of ordinary skill in the art can easily determine, with the protocols given in the specification, whether a given compound has the utility stated. Thus, the mere fact that many compounds must be tested is not dispositive of lack of utility.

Thus, objective enablement is clearly present, and withdrawal of the rejection under 35 U.S.C §112 is respectfully requested.

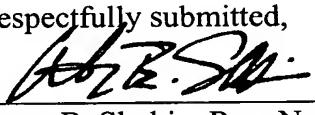
Claims 1-5, 7-9 and 12-23 have been rejected 35 U.S.C. §112, second paragraph, as being indefinite. Various grammatical and typographical changes have been made to the claims,

it is submitted that these rejections are moot. With respect to the moiety phenyl-$(CH_2)_p$-R^{10}, it is believed evident from the specification that the point of attachment is at any free position on the phenyl ring. It is submitted that these rejections, in view of the clarifying amendments, are also moot, and withdrawal thereof is respectfully requested.

The claims in the application are submitted to be in condition for allowance. However, should the examiner have questions or comments, he or she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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